December 14, 1992

AMENDMENT TO (REVISION NO. 3)

QUALITY ASSURANCE PROJECT PLAN (QAPjP)

for

EFFICACY OF REPAIR AND MAINTENANCE INTERVENTIONS

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Quality Assurance Plan
for the
Lead Paint Abatement and Repair & Maintenance
Study in Baltimore

Contract Number: 68-DO-0126

APPROVAL FOR KENNEDY KRIEGER INSTITUTE:

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Bruce Buxton, Project Manager — 12/11/92 Date

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SUMMARY OF REVISIONS

The Quality Assurance Project Plan (QAPjP) (Revision 3) for the Lead-Based Paint Abatement and Repair and Maintenance Study was approved by EPA on August 4, 1992. Battelle and Kennedy Krieger Institute (KKI) met with EPA staff on August 12, 1992 and September 9, 1992 to discuss revisions to the study design. It was agreed at the September 9, 1992 meeting that an amendment to the current QAPjP would be used to document study revisions. Several modifications were made to QAPjP based on the two meetings held at EPA and subsequent conference calls between EPA, Battelle, and KKI. Major revisions were made to the experimental design of the study, sample collection of dust samples, and analysis of blood samples. Minor modifications were made to several analytical protocols and field collection forms. This amendment documents modifications to Revision Number 3 of the QAPjP.

Revisions are summarized in this section. Subsequent sections provide details on the actual modifications; additions and revisions are highlighted to facilitate review of the changes. In addition, key tables are reproduced in this section to enhance readability.

Revisions to the experimental design incorporate suggestions of EPA, Battelle, and Kennedy Krieger Institute staff regarding strategies for reducing the scope of work to match available resources while preserving the essential features of the study design. Multiple strategies were employed to reduce the total number of samples collected and analyzed. The number of control dwellings was reduced from 25 to 15 for both modern urban and previously abated dwellings. Table 2.1 displays the number of homes now planned for the study. The number of follow-up campaigns was reduced by one by combining the 1 month and 3 month post-R&M sampling campaigns into a single sampling campaign at 2 months post-R&M. Table 2.2 presents the revised sampling campaigns. In addition, a subset of the 60 R&M dwellings will be selected for environmental sampling at the 2, 6, 12, 18, and 24 month post-R&M sampling campaigns.

While the above strategies reduce the number of sampling visits to dwellings, strategies were also employed to reduce the number of samples collected and analyzed per home. Table 2.4 displays the environmental samples planned for each sampling campaign. Air duct/upholstery vacuum-dust samples, exterior entryway vacuum-dust samples and some soil samples will be collected and stored for future analysis. Increased use of sample compositing reduces the total number of samples collected per home. Side-by-side field samples of dust, soil and water will be collected from only 10 percent of the homes, as opposed to every home. Because this study comprises a large number of homes, 105, and sampling campaigns, five and seven for control and R&M homes, respectively, sufficient data remains for estimating the variability of environmental sampling. A new section, Section 2.4, has been added on the effects of reduction in study size. The reduction in the number of samples is expected to have little impact on the ability of the study to detect differences in blood- or environmental- lead among the study groups.

The substudy comparing wipe and vacuum methods for collecting dust will be conducted in vacant older dwellings and a modern dwelling not included in the main study. This change was made so that the substudy would not present an extra burden on participants of the main study.

The cost caps for Repair and Maintenance have been increased slightly for R&M levels I and III.

Blood samples will be analyzed using anodic stripping voltammetry (ASV) for clinical monitoring purposes and by graphite furnace atomic absorption spectrometry (GFAA) for research purposes. Analysis of blood samples by GFAA was suggested by the EPA Work Assignment Manager. It is expected that GFAA methods will be more precise and accurate than ASV methods. Samples will be run by both ASV and GFAA methods until it is determined, based on QC data, that analysis by GFAA alone is sufficient.

Format of the questionnaire was revised, and sample collection and traceability forms were updated. Protocols were updated for gravimetrics, collection of wipe-dust, soil, and drinking water samples, preparation and digestion of samples, preparation and handling of reference materials, and preparation of glassware. Protocol for vacuum-dust sampling was rewritten due to the change in samplers, and a new protocol was composed for the analysis of blood samples using GFAA.

TABLE 2.1 Number of Dwellings Planned for Recruitment by Study Group

STUDY GROUP	NUMBER OF DWELLINGS
PREVIOUSLY ABATED	15
REPAIR & MAINTENANCE	
Level I	25
Level II	25
Level III	25
MODERN URBAN CONTROLS	15
TOTAL	105

TABLE 2.2 Frequency of Follow-up

STUDY GROUP	PRE[1]	POST[1]	ENROLL[2]	2 MO	6 MO	12 MO	18 MO	24 MO	No. of Campaigns
Previously Abated			YES		YES	YES	YES	YES	5
R&M Levels I, II and III	YES[3]	YES[3]		YES[4]	YES[4]	YES[4]	YES[4]	YES[4]	7
Modern Controls			YES		YES	YES	YES	YES	5

1. Pre = Pre-intervention
   Post = Immediate post-intervention
   Enroll = Enrollment

2. Enrollment will be done at a point in time 2-to-3 years post-abatement. Pre-abatement and post-abatement clearance dust-lead data are available to KKI. (Dust was collected by wet wipe and analyzed by flame AAS after HCl extraction).

3. Environmental data is planned for collection in all 75 R&M dwellings.

4. Environmental data is planned for collection in 60 R&M dwellings
   (20 dwellings in each of the three levels of R&M).

Table 2.4A

Summary of Environmental Sampling Planned per R&M Dwelling by Campaign[i]

Sample Type	Pre-R&M	Post-R&M	2 Mo	6 Mo	12 Mo	18 Mo	24 Mo
Vacuum-Dust							
Perimeter floor composite	3.0	3.0	3.0	3.0	3.0	3.0	3.0
Window sill composite	2.0	2.0	2.0	2.0	2.0	2.0	2.0
Window well composite	2.0	2.0	2.0	2.0	2.0	2.0	2.0
Air duct/upholstery	(1.0)[a,b]	-	(1.0)[a,c]	-	(1.0)[a,b]	-	(1.0)[a,b]
Int. Entrance	1.0	1.0	1.0	1.0	1.0	1.0	1.0
Ext. Entrance	(1.0)[a]	-	-	(1.0)[a]	-	(1.0)[a]	-
Soil Cores							
Near foundation	1.0	1.0	-	1.0	-	(1.0)[a]	-
Property boundary	-	-	-	(1.0)[a]	-	-	-
Drinking Water	1.0	-	-	1.0	-	(1.0)[a]	-
Wipe-Dust	-	3.0[g]	-	-	-	-	-
Wipe vs. Vacuum[d]	-	-	-	-	-	-	-
Field QC							
Vacuum-dust blank	1.0	1.0	1.0	1.0	1.0	1.0	1.0
Vacuum-dust duplicate	0.1	0.1	0.1	0.1	0.1	0.1	0.1
Soil blank/duplicate	1.1[e]	1.1[e]	-	1.1[e]	-	1.1[e]	-
Water blank/duplicate	1.1[e]	-	-	1.1[e]	-	1.1[e]	-
Wipe dust blank & duplicate[d]	-	-	-	-	-	-	-
Total Collected for Analysis	12.3	13.7	9.1	12.3	9.1	10.3	9.1
Total Collected and Stored	3.0[f]	0.5[f]	1.0[e]	3.0[f]	1.0	4.0[f]	1.0
Total Samples[h]	15.3	14.2	10.1	15.3	10.1	14.3	10.1

[i] Collected, prepared and stored for later analysis.

[b] Sample Air Duct if possible, if not then collect upholstery sample.

[c] Collect only upholstery samples in homes that did not have such a sample at Pre-R&M.

[d] Seventy-five pairs of side-by-side wipe/vacuum dust samples from floors, window sills & window wells will be collected as a substudy in a separate group of dwellings; field blanks and duplicates will be included.

[e] This includes 1.0 field blanks (50% will be analyzed, 50% will be stored) and 0.1 field duplicates.

[f] See footnote "e" for soil and water QC.

[g] Estimated average number of wipe samples required by the Maryland Department of the Environment for regulatory purposes. (Expected range 2-10 samples per unit.)

[h] Pre- & Post-R&M campaigns will include all 75 R&M dwellings. Follow-up campaigns will include 60 R&M dwellings (20 dwellings of each R&M level).

[i] All 75 R&M dwellings will be sampled at Pre- and Post-R&M. Sixty R&M dwellings will be sampled at each follow-up campaign (20 dwellings each of R&M Levels I-III.

Table 2.4B

Summary of Environmental Sampling Planned per Modern and Previously Abated Control Dwelling by Campaign

Sample Type	Enroll	2nd Campaign	3rd Campaign	4th Campaign	5th Campaign
Vacuum-dust					
Perimeter floor composite	3.0	3.0	3.0	3.0	3.0
Window sill composite	2.0	2.0	2.0	2.0	2.0
Window well composite	2.0	2.0	2.0	2.0	2.0
Air duct/upholstery	(1.0)[a,b]	(1.0)[a,c]	(1.0)[a,b]	-	(1.0)[a,b]
Int. Entrance	1.0	1.0	1.0	1.0	1.0
Ext. Entrance	(1.0)[a]	(1.0)[a]	-	(1.0)[a]	-
Soil Cores					
Near foundation	1.0	1.0	-	(1.0)[a]	-
Property boundary	-	(1.0)[a]	-	-	-
Drinking Water	1.0	1.0	-	(1.0)[a]	-
Field QC					
Vacuum-dust blank	1.0	1.0	1.0	1.0	1.0
Vacuum-dust duplicate	0.1	0.1	0.1	0.1	0.1
Soil blank/duplicate	1.1[d]	1.1[d]	-	1.1[d]	-
Water blank/duplicate	1.1[d]	1.1[d]	-	1.1[d]	-
Total Collected for Analysis	12.3	12.3	9.1	10.3	9.1
Total Collected and Stored	3.0[e]	4.0[e]	1.0	4.0[e]	1.0
Total Samples	15.3	16.3	10.1	14.3	10.1

[a] Collected, prepared and stored for later analysis.
[b] Sample air duct if possible, otherwise collect upholstery sample.
[c] Collect only upholstery sample in homes that did not have such a sample at Enrollment.
[d] This number includes 1.0 field blanks (50% will be analyzed, 50% will be stored) and 0.1 field duplicates.
[e] See footnote "d" for soil and water QC.

2.1 Project Description

In this study, the efficacy of lead-paint abatement work performed according to Maryland regulations (see Appendix B) by special pilot projects using trained and dedicated crews will be characterized and compared to that of three levels of Repair and Maintenance interventions in older lead-painted dwellings. Each of the three levels of R&M (low, medium, and high) will be used separately in groups of 25 dwellings each, with 15 modern (post-1980) and 15 previously abated dwellings acting as controls. Thus, there will be 5 study groups and a total of 105 dwellings. Section 2.3.1.5 provides a description of R&M interventions. The following sections include descriptions of the study objectives, hypotheses, data quality objectives, experimental design, sampling frames for dwellings, and project organization.

2.1.3 Statement of the Data Quality Objectives

Sample Sizes:
Blood-Lead

With regard to blood-lead changes, we will be looking for proportionate changes in blood-lead concentrations. It is very difficult to project power to detect blood-lead changes since we have at present, no firm idea of the exact number of children that will be enrolled in the study. Our goal is to enroll at least one child aged six months through four years in each study dwelling for a total of at least 105 children in 105 dwellings. Sections 2.1.6 and 2.3.1.3 describe measures to be taken to increase the likelihood that study dwellings will be occupied by at least one young child between the age of 6 months through 4 years of age.

Assuming an n of 20 children, we find using a standard deviation of ln blood-lead of 0.47 (corresponding to a geometric standard deviation of (GSD) of 1.6)[21] that delta is given by

$$\text{delta} = \frac{3.96 \times 0.47}{\text{sqrt}\ (20)}$$

$$= 0.42 \quad \text{on a log scale.}$$

This assumes a two group comparison and uses the usual sample size formula.

It follows that we have power .8 to detect a change of .42 in log blood-lead levels or a proportional change of 52 percent in actual blood-lead level. Using a GSD of 1.42 which implies the standard deviation of ln(blood-lead) is 0.35, we calculate a delta of 0.310 on a log scale (or proportional change of 36 percent).

If the baseline blood-lead concentration of children in R&M dwellings is 13 µg/dL, then we would be able to detect a change of ± 6.8 µg/dL (± 52%), which represents an increase to a level of concern under the new CDC guidelines, 19.8 µg/dL, or a decrease to 6.2 µg/dL.

Measurement of Lead in Blood Samples

Specific data quality objectives for measurement of lead in blood by anodic stripping voltammetry (ASV) are as follows:

- Accuracy within ± 2 µg/dL on secondary standards run after every set of four measurements as continuing calibration verification samples. Accuracy within ± 2 µg/dL on external proficiency testing samples sent to the Trace Metal Laboratory by the CDC blood-lead proficiency testing program;
- Analytical precision: standard deviation of 1.6 µg/dL for replicate injections of the same sample; and,
- Completeness of data ≥ 95% (i.e. 95% of data collected is analyzed to completion and available for data analysis).

The estimated limit of detection for blood specimens analyzed by anodic stripping voltammetry (ASV) using the ESA 3010-A is approximately 3 µg Pb/dL. It has a linear response up to 150 µg Pb/dL.

Specific data quality objectives for measurement of lead in blood by graphite furnace atomic absorption spectrometry (GFAA) are as follows:

- Accuracy within ± 2 µg/dL on NIST reference materials - SRM#955. Accuracy within ± 2 µg/dL on external proficiency testing samples sent to the Trace Metal Laboratory by the CDC blood-lead proficiency testing program;
- Analytical precision: standard deviation of 1.6 µg/dL for replicate injections of the same sample; and,
- Completeness of data ≥ 95% (i.e. 95% of data collected is analyzed to completion and available for data analysis).

The estimated limit of detection for blood specimens analyzed by GFAA using the Perkin Elmer 5100 instrument is approximately 1 µg Pb/dL. The instrument is calibrated using six standards up to 50 µg Pb/dL. As the TML accumulates historical QC data from internal and external QC programs, the performance data using GFAA is expected to show an improvement over ASV in terms of accuracy and precision.

2.1.4 Brief Description of Experimental Design

This prospective study has two main components and a total of five groups of study houses. The first component is designed to obtain serial measurements of lead in venous blood of children 6 months through 4 years of age, house dust, soil and drinking water in three groups of 25 dwellings (total of 75 dwellings), each receiving one of three levels of Repair & Maintenance interventions. Measurements of lead in blood in children in all 75 R&M study dwellings will be obtained at the following times: pre-intervention, immediately post-intervention, and 2, 6, 12, 18, 24 months post-intervention. Measurements of lead in vacuum dust samples in all 75 R&M study dwellings will be obtained at pre- and immediate post-intervention; 60 R&M dwellings (20 in each of the three R&M groups) will be included in the follow-up environmental sampling campaigns for vacuum dust as follows: 2, 6, 12, 18, 24 months post-intervention. Measurements of lead in exterior soil will be obtained at pre-intervention, immediately post-intervention, and 6 and 18 months post-intervention. Measurements of lead in drinking water will be obtained at pre-intervention, and 6 and 18 months post-intervention. The study questionnaire, designed to obtain information on demographics, and covariates which could influence lead exposure in the home (e.g. hobbies, child behavior, diet and occupation) will be done at enrollment and again at six month intervals (see Appendix E). Variables not measured at every time point will be considered constant between intervals (e.g. water and soil lead levels in the absence of abatement/treatment). Data on the costs of R&M interventions will be available to the Kennedy Krieger Institute from City Homes and from the Maryland Residential Lead Paint Abatement Program which will be financing the R&M work.

Occupied dwellings will be randomly assigned to receive either R&M Level I or R&M Level II intervention in a ratio of 2:1, respectively. Dwellings vacant at the time of intervention will be randomly assigned to receive R&M Level III or Level II interventions, in a ratio of 2:1, respectively. Since R&M Level II interventions will be done in both occupied and vacant units these ratios will ensure that equal numbers of dwellings (n=25) are

assigned to each R&M treatment level (see Table 2.1). This randomization will be done by the Project Manager (see section 2.3.1.7 for details of the randomization scheme).

The second component of the study design is to obtain serial measurements of lead in venous blood of children 6 months through 4 years of age, house dust, soil and drinking water in a sample of 15 dwellings which received comprehensive lead-paint abatement performed by pilot abatement projects in Baltimore between May of 1988 and February of 1991. Measurements of lead in blood and vacuum-dust samples will obtained at the following times: enrollment and 6, 12, 18, and 24 months post-enrollment. Measurements of lead in exterior soil and drinking water will obtained at enrollment and at 12 and 24 months post-enrollment. The study questionnaire, will be done at enrollment and again at six month intervals.

These abatements form the basis for a natural experiment in a fourth study group. Two years of planned follow-up will provide an opportunity to measure their efficacy out to four to six years post-abatement. These types of long-term follow-up data currently do not exist, yet they are essential for developing scientifically sound prevention and remediation policies. Pre-abatement and post-abatement dust-lead data from dwellings abated by City and Kennedy Krieger Institute abatement projects are available to the investigator and provide useful baseline information for this study. Pre-abatement and post-abatement dust samples were collected from floors, window sills and window wells by sanitarians or environmental inspectors working for the Baltimore City Health Department or the Maryland Department of the Environment using the wet wipe technique as previously described[12]. Dust was analyzed for lead content by the method previously described[12] (HCl extraction) by the Maryland Department of Health and Mental Hygiene. Results were reported in $\mu g/ft^2$.

A group of 15 modern urban dwellings built after 1980, the fifth study group, will be studied as negative controls (i.e. dwellings which are not likely to contain lead-based paint). The types of measurements and the frequency of collection campaigns

will be the same as those for previously abated dwellings This study does not include positive controls (older lead-painted dwellings which receive no intervention) for ethical reasons. This study does not want to be in a position of only monitoring lead levels in dwellings with potentially high PbD levels.

Table 2.1 summarizes the number of dwellings planned for recruitment by study group. Table 2.2 (revised) provides a summary of data collection campaigns by study group. More frequent sampling campaigns are planned for R&M dwellings during the first year compared to other study groups. This is due to the fact that we have little data on these types of interventions. We want to be able to estimate the rate of reaccumulation of lead in dust after intervention and to determine early on if adjustments need to be made in the R&M designs or if further cleanups and repairs are needed over time (see section 2.3.1.6).

For houses in the R & M study groups data will be collected at the following times:

T_1 - immediately before R & M
T_2 - immediately post R & M
T_3 - 2 month after R & M
T_4 - 6 months after R & M
T_5 - 12 months after R & M
T_6 - 18 months after R & M
T_7 - 24 months after R & M

For houses in the modern and previously abated groups data will be collected at times T_1 (enrollment), T_4, T_5, T_6, and T_7 (Specific data to be collected is described in Tables 2.3 and 2.4A/B). The design of this study includes the testing of blood-lead levels of all eligible children aged 6 months through 4 years in each study dwelling. Section 5.2 describes how this will be handled in the data analysis.

2.1.5 Summary of Quality Control Steps to Ensure Data Quality

The following is a summary of quality control steps to ensure data quality.

1. Conduct the study according to the Quality Assurance Project Plan.

2. Control for sampling variability by collecting dust samples from 25 dwellings in each R&M study group and from 15 dwellings in each control group (modern and previously abated and from multiple rooms within each dwelling and from floor, window sill and window well surfaces within rooms.

3. Collect field QC samples (side-by-side samples and field blanks) to estimate variability in sampling procedures and lead contamination introduced during field sampling.

4. Implement a program of laboratory QC which includes the analysis of spiked samples, spike duplicates, standard reference materials, method blanks, and calibration verification and calibration blank samples.

5. Chart results of the analysis of laboratory QC samples on control charts with warning and control limits indicated.

6. Conduct field and laboratory system, performance and data audits. This will be done by the Lab QC Officer.

7. Implement a sample tracking system to enable samples to be traced from the field through the laboratory.

8. Arrange for double keypunch entry of data from preprinted field collection and questionnaire forms.

TABLE 2.1

Number of Dwellings Planned for Recruitment by Study Group

STUDY GROUP	NUMBER OF DWELLINGS
PREVIOUSLY ABATED	15
REPAIR & MAINTENANCE	
Level I	25
Level II	25
Level III	25
MODERN URBAN CONTROLS	15
TOTAL	105

TABLE 2.2

Frequency of Follow-up

STUDY GROUP	PRE[1]	POST[1]	ENROLL[2]	2 MO	6 MO	12 MO	18 MO	24 MO	No. of Campaigns
Previously Abated			YES		YES	YES	YES	YES	5
R&M Levels I, II and III	YES[3]	YES[3]		YES[4]	YES[4]	YES[4]	YES[4]	YES[4]	7
Modern Controls			YES		YES	YES	YES	YES	5

1. Pre = Pre-intervention
   Post = Immediate post-intervention
   Enroll = Enrollment

2. Enrollment will be done at a point in time 2-to-3 years post-abatement. Pre-abatement and post-abatement clearance dust-lead data are available to KKI. (Dust was collected by wet wipe and analyzed by flame AAS after HCl extraction).

3. Environmental data is planned for collection in all 75 R&M dwellings.

4. Environmental data is planned for collection in 60 R&M dwellings (20 dwellings in each of the three levels of R&M).

In addition to these steps the R&M Field QC Officer will participate in the development of R&M work plans for each study dwelling to ensure that the work is designed according to study specifications. This will help maintain the homogeneity of R&M specifications across contractors and dwellings. The R&M QC Officer will also be responsible for checking that the actual work is performed according to the work plans.

2.1.8 Anticipated Duration and Cost of Project

The anticipated duration of the data collection and analysis phases of this project is 4 years beginning December 15, 1992 (see Figure 1 below for revised project schedule). The actual duration will depend in part on the time required to enroll the R&M dwellings and carry out the 75 R&M interventions. We anticipate this to take up to seven months, and perhaps longer as explained in section 2.1.6. The anticipated cost of the project will be provided at a later time. The final six months is for completion of laboratory analyses, data analysis, and preparation of the final report.

The budget is in part determined by what may be viewed as the fixed costs of:

a. Supporting sufficient numbers of outreach personnel needed to be able to complete the major data collection campaigns in the required time frames (total of over 1200 home visits to study dwellings).

b. Supporting the laboratory personnel and equipment needed in order to prepare and analyze large numbers of environmental samples (approximately 8000 samples over three years) plus the associated laboratory preparation and instrumental QC samples (over 2,000 additional measurements) by a relatively labor intensive method in a reasonable time-frame (e.g. to be able to analyze the dust samples collected in one data campaign prior to the start of the next data campaign).

c. Supporting data management, computer programming, statistical consulting and QC staff needed for a project of this size and complexity.

2.2 Project Organization and Management

Figure 2 is a revised organizational chart for the project.

2.2.1 Project Responsibilities and Authority

Listed below are additional key project personnel not named in the earlier QAPjP:

Mr. William Derbyshire, Project Manager, will be responsible for the day-to-day operations, including maintaining the project schedule, maintaining communications with collaborating organizations and the various study components, preparing and monitoring budgets, and assisting in the preparation of reports and other project deliverables. This includes assistance in the preparation of detailed monthly progress reports and briefing materials.

Mr. Brian Rooney will serve part-time as the data manager/computer programmer for the study. Responsibilities will include, designing and managing the various databases, and performing computer programming for data management and data analysis according to instructions from the statistical consultant and M. Farfel. This will include developing and performing the data transfer processes required for data management and analysis; production of the QC charts and design of data collection forms.

2.2.2 Personnel Qualifications

Summaries of qualifications are provided below for additional key project personnel not named in the previous version of the QAPjP. Resumes are provided in Appendix F.

Mr. William Derbyshire possess a Bachelor's degree in Jurisprudence (cum laude) and has completed 30 credits towards a Master of Public Administration degree. Mr. Derbyshire has extensive management, report writing, and supervisory experience. He has worked as business manager of a firm providing mental health services and as general manager and vice president of private sector businesses. He also has extensive experience working with community organizations and local government. Mr. Derbyshire has knowledge of computer systems (PC, and Network) and numerous software packages for database management, presentation graphics, word processing, and spreadsheets.

Mr. Brian Rooney holds a B.A. degree and is currently in a masters level degree program in computer science. Over the last four years Mr. Rooney has been employed at the Johns Hopkins University School of Hygiene and Public Health as a senior program analyst working on the design and development of three large occupational health and epidemiologic databases. His responsibilities included data

FIGURE 1: WORK PLAN

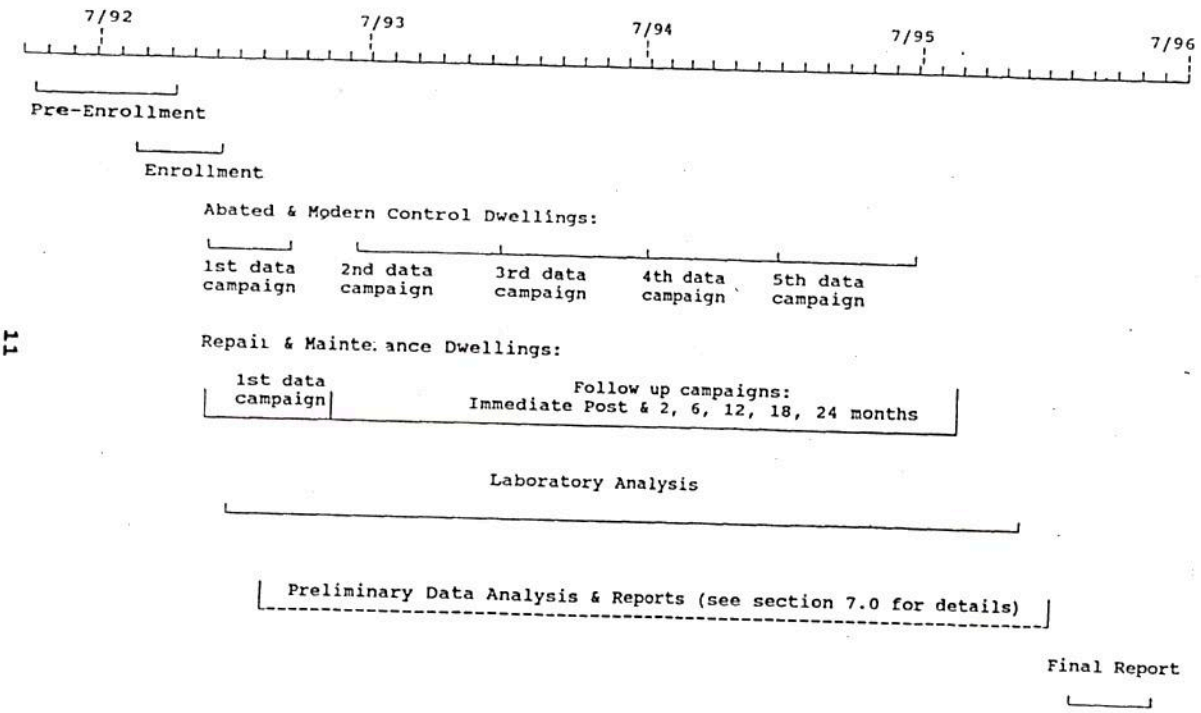
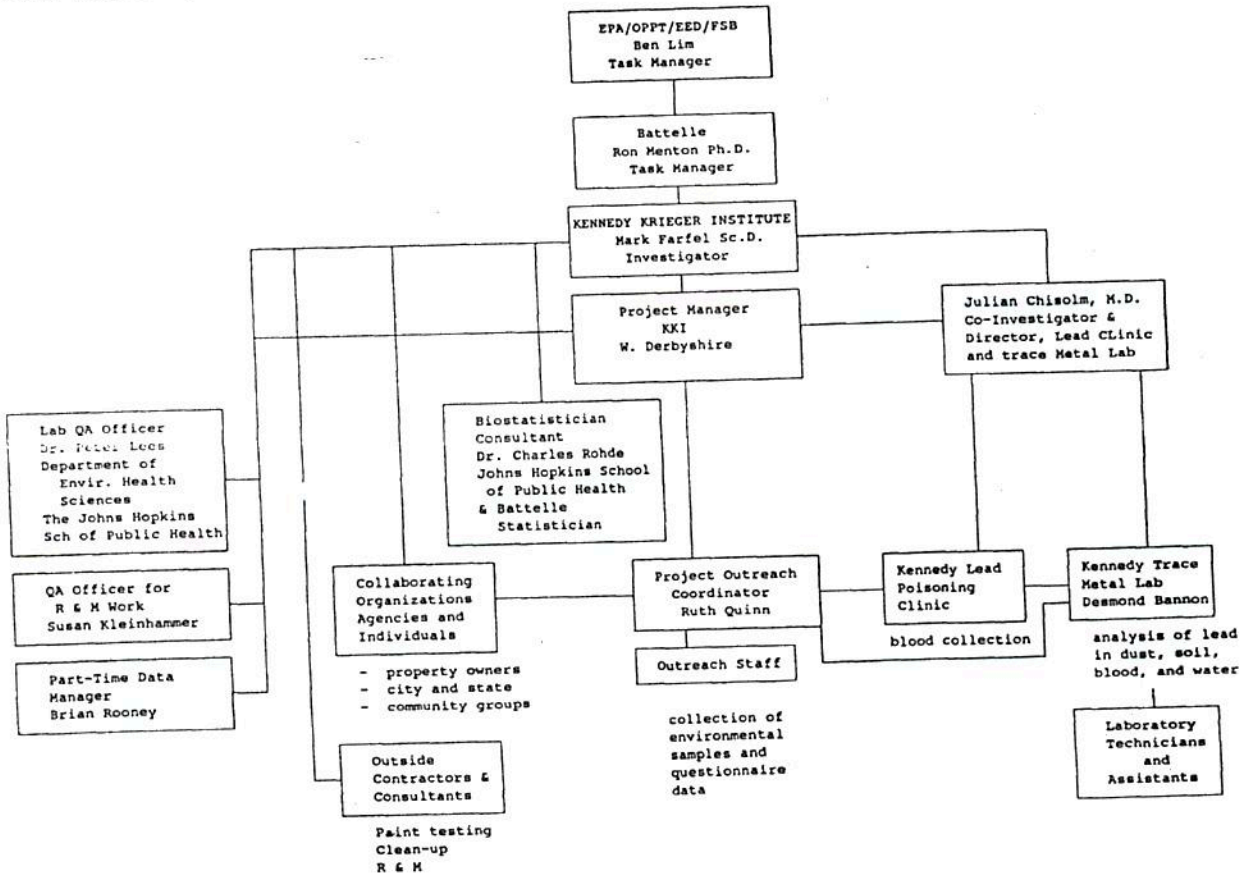


FIGURE 2: Project Organization and Management



management and data analysis. Mr. Rooney also manages two VAX systems and runs a local network system associated with the Department of Environmental Health Sciences. Mr. Rooney has experience in Pascal, SAS, PAL languages and knowledge of both IBM/PC and VAX/VMS operating systems.

2.3.1.2 Sampling Plan

Table 2.3 provides a summary of the data collection planned by sampling campaign and by study group. Figure 3 shows the data collection schedule by campaign. Table 2.4A/B is a summary of the environmental sampling by campaign, including quality control samples, per R&M and control dwellings respectively. For R&M and modern control dwellings, enrollment measurements will provide baseline levels of lead in house dust, soil, drinking water and children's blood. Enrollment measurements in previously abated dwellings will represent measurements at 2-to-4 years post abatement. Previously collected pre- and post-abatement wipe-dust data will serve as baseline levels of lead in house dust (see section below on comparison of wipe and vacuum samples). The range in number of environmental samples per study dwelling per campaign is 10.1 to 16.3 samples (see Tables 2.4A/B).

Our typical study dwelling will be a two-story row home in Baltimore (approximately 800 to 1200 square feet) with three rooms on each level and at least one window in the front and back rooms on each floor. Some, but not all, dwellings will have windows in one or both of the middle rooms.

Since the compositing substudy of the R&M Pilot Study suggested that variability of vacuum-dust-lead measurements across rooms is small compared to within room variability for floor samples, compositing will be performed over rooms as a means of reducing the total number of samples collected in the main study.[17] Our sampling plan for floor vacuum-dust samples is to collect three composite floor samples per dwelling: one across rooms with windows on the first floor, one across rooms with windows on the second floor and one from first and second floor rooms without windows. Two randomly selected 1-ft^2 subareas along the perimeter of the floor would be sampled in each room included in a composite sample.

Low-level dust loadings observed on window sills in the Pilot Study indicated the need to sample larger areas in the main study to help ensure the collection of at least 10 mg of dust. The Pilot Study also suggested that window sills had the least amount of variability within dwellings compared to window wells and floors. Consequently, our sampling plan for window sills calls for the collection of one first floor composite of all window sills available for sampling and one second floor composite of all window

sills available for sampling. The sampling plan for window wells will be the same as that described above for window sills (i.e. first and second floor composites; see section 8.0 for definition of window well). Other sampling sites for vacuum-dust are air ducts (one randomly selected supply air duct), and interior and exterior entry ways.

Soil core samples will be collected from near the foundation and at the property boundary. Drinking water samples (2-hour fixed-time stagnation samples) will be collected at enrollment and at 6 and 18 months. The pilot study and other work has suggested that water-lead levels in Baltimore are generally low. However, water-lead which can be an important source of exposure for children needs to be taken into account as a covariate when modelling changes in children's blood-lead concentrations.

Testing for lead in dust and blood is planned at six month intervals in abated dwellings and modern control dwellings in order to control for possible seasonal effects on levels of lead in dust and children's blood. Sampling campaigns are planned during the late spring/summer and the winter seasons when the lead levels in dust and children's blood are expected to be at relatively high and low levels, respectively. All eligible children 6 months through 4 years of age in each household will be recruited for blood-lead testing.

More frequent sampling of dust in R&M dwellings is proposed during the first year of follow-up after intervention. This is due to the fact that we have no pilot dust-lead data over time following R&M interventions. More frequent sampling during the first year post-intervention (i.e. at 2 mo. 6 mo. and 12 mo.) would give us the ability to review early findings early in the study period and make additional repairs and changes as needed in the work specifications for subsequent interventions.

Comparison of Wipe and Vacuum-dust

The Kennedy Krieger Institute (KKI) has conducted past studies on changes in dust-lead levels in homes following alternative abatement procedures.[12,13] However, little is known about the relationship between the methods of dust collection (alcohol wipes) and analysis (extraction using 0.1 N HCl and analysis by flame atomic absorption spectrometry) used in past KKI studies and those which will be employed in this study (vacuum collection using a modified HVS_3 cyclone collector, sample preparation using nitric acid and analysis by ICP). A substudy conducted as part of the R&M Pilot Study showed a strong relationship between wipe samples of the type used in past Kennedy Krieger Institute studies and vacuum-dust samples collected using a different collection device. An equation was developed to relate wipe measurements to vacuum

measurements. However, this type of substudy needs to be repeated as part of the main study using the vacuum collection device proposed for this study (cyclone sampler attached to a Dirt Devil vacuum).

A total of 75 pairs of side-by-side wipe and vacuum samples (25 pairs each from floors, window sills and window wells) will be collected from vacant older dwellings and a modern dwelling not included in the main study. In all cases, the vacuum sample will be collected last to reduce the likelihood of the vacuum pulling dust from the surface designated for wipe collection. In the case of windows, wipe samples will be collected first from the right or left half of the surface (selected randomly). This sample size will enable us to place a confidence interval of approximately ± .20 on the correlation coefficient.

These results will be used to model the relationship between wipe and vacuum samples for the three surface types. This information will be used to predict what the vacuum lead measurements would have been in previously abated study dwellings based on pre and post-abatement dust wipe measurements which are available to the Kennedy Krieger Institute. The predicted vacuum lead measurements at pre- and post-abatement will be compared to the follow-up measurements taken in this study.

2.2.1.3 Sampling Frame for Dwellings

Previously Abated Dwellings

Replace the first sentence of the first paragraph to read as follows:

The sampling frame for previously abated dwellings consists of 90 low-income housing units in Baltimore City abated between May of 1988 and April of 1992 by Baltimore City and Kennedy Krieger Institute Pilot Abatement Projects according to Maryland's 1988 regulations using trained work crews. At least six pairs of pre- and immediate post-abatement dust wipe lead measurements from the same floor, window sill and window well surfaces are available from 49 of the 90 previously abated dwellings (see Section 2.3.1.4, selection criterion number 9).

Dwellings which will Receive R&M Interventions

Replace the first sentence of the first paragraph to read as follows:

The primary sampling frame for dwellings that would receive R&M interventions will consist of older (mostly pre-1940) low-

income rental units in Baltimore City owned by City Homes. Inc. and State Realty, a privately owned firm.

Modern Urban Control Dwellings

The following three subdivisons will also be included in the sampling frame:

5. Coldstream-Homestead-Montebello, 70 homes
6. Sandtown-Winchester
7. Penn North

2.3.1.5 Description of R&M Levels I-III

The cost caps for Repair & Maintenance work have been revised as follows: Level I to $1,650 from $1,500; Level III to $7,000 from $6,000 per two-story row house (approximately 800 to 1200 square feet). These revisions, approved by KKI, resulted from negotiations between City Homes and the Maryland Department of Housing and Community Development.

2.3.1.11 Summary of Approach to Incentives for Participation by Families

In the Pilot Study, we found that payment of $15 for completion of the questionnaire interview was looked upon very favorably by study participants. In consultation with the Maryland Department of Environment (MDE), Maryland Lead in Soil Project, we have gained an overview of the types of incentives that were most effective in recruiting and retaining family participation over an extended period of time and have incorporated them in our plan. At this point in time the following incentives are planned for this study.

1. Coupons, for things ranging from skating trips to groceries, which serve as an initial incentive for families to enroll in the program.

2. Gifts for the children such as T-shirts in the summer, and hats and gloves during winter clinic appointments.

3. Providing parents with ongoing incentives such as $10.00 food coupons at each visit at the clinic for blood collection.

4. $1.00 - $2.00 gift certificates for toys.

TABLE 2.3
Summary of Data Collection Planned for the R&M Study[1]

Sampling Campaign	R & M Units Occupied at Intervention	R & M Units Vacant at Intervention	Previously Abated Units	Modern Control Units
Enrollment/ Pre-Intervention	DV, S, W, Blood, Q	DV, S, W	DV, S, W, Blood, Q,	DV, S, W, Blood, Q
Immediate Post-Intervention	DV, S	DV, S	Not Applicable	Not Applicable
At-Time Family Moves In	Not Applicable	Blood, Q	Not Applicable	Not Applicable
2 months	DV, Blood	DV, Blood	-----	-----
6 months	DV, S, W, Blood, Q^2	DV, S, W, Blood, Q^2	DV, S, W, Blood, Q^2	DV, S, W, Blood, Q^2
12 months	DV, Blood, Q^2	DV, Blood, Q^2	DV, Blood, Q^2	DV, Blood, Q^2
18 months	DV, S, W, Blood, Q^2	DV, S, W, Blood, Q^2	DV, S, W, Blood, Q^2	DV, S, W, Blood, Q^2
24 months	DV, Blood, Q^2	DV, Blood, Q^2	DV, Blood, Q^2	DV, Blood, Q^2

1. DV = Vacuum-dust W = Drinking Water S= Soil Core
Q = Questionnaire.
Side-by-side wipe/vacuum dust samples will be collected as a substudy in a separate group of dwellings.
2. In subsequent visits to homes we will update questions for items that change over time.

Figure 3

R & M QAPjP Revisions
Chapter 2
Revision No. 3
Date: November 24, 1992

KKI R&M Project
DATA COLLECTION CAMPAIGN SCHEDULE

LEGEND
PI = Pre-Intervention campaign
PO = Post-Intervention campaign
EN = Enrollment
nC = Campaign number
n MO = Follow-up campaigns
R&M = Repair & Maintenance

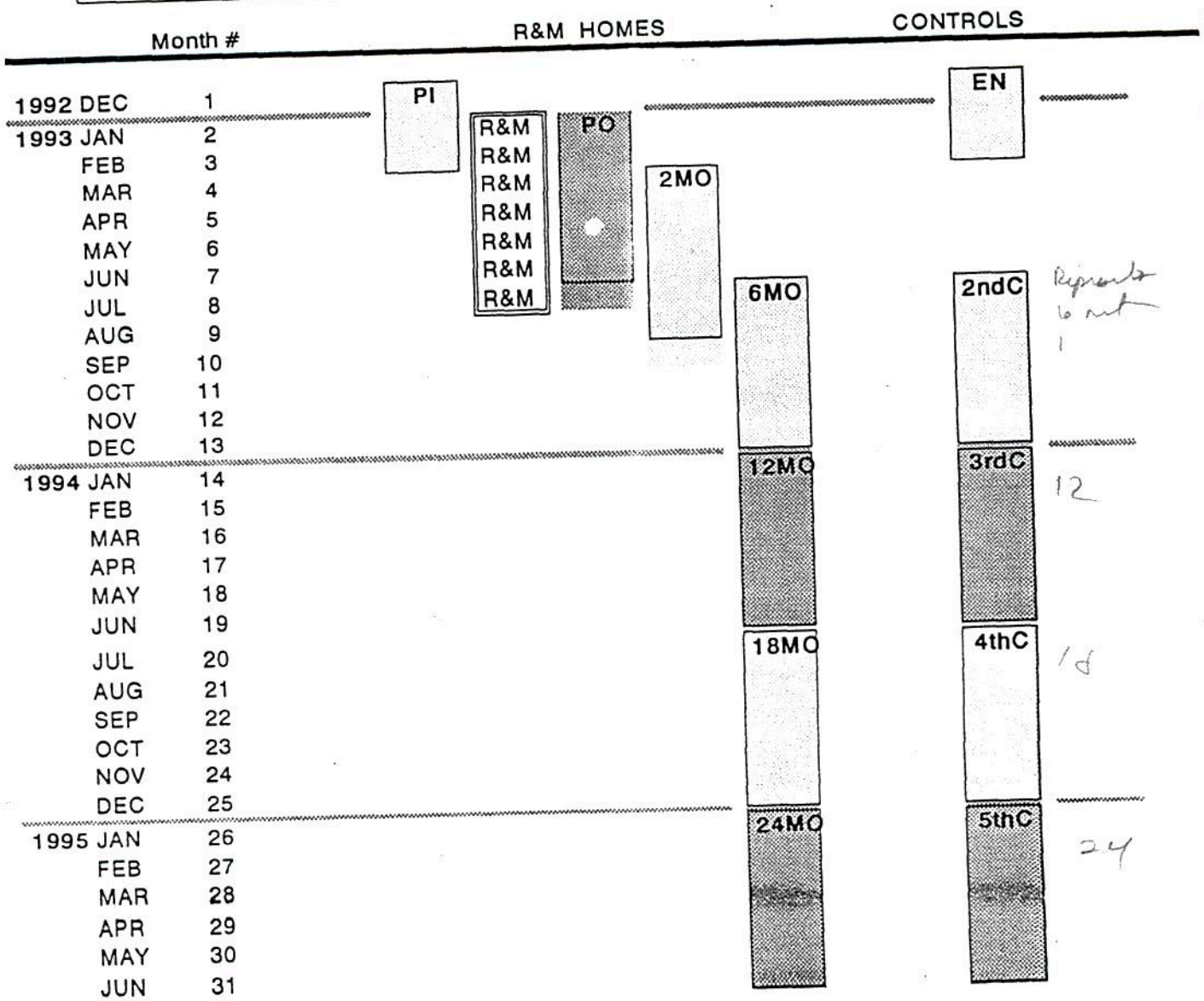


Table 2.4A Summary of Environmental Sampling Planned per R&M Dwelling by Campaign[i]

Sample Type	Pre-R&M	Post-R&M	2 Mo	6 Mo	12 Mo	18 Mo	24 Mo
Vacuum-Dust							
Perimeter floor composite	3.0	3.0	3.0	3.0	3.0	3.0	3.0
Window sill composite	2.0	2.0	2.0	2.0	2.0	2.0	2.0
Window well composite	2.0	2.0	2.0	2.0	2.0	2.0	2.0
Air duct/upholstery	(1.0)[a,b]	-	(1.0)[a,c]	-	(1.0)[a,b]	-	(1.0)[a,b]
Int. Entrance	1.0	1.0	1.0	1.0	1.0	1.0	1.0
Ext. Entrance	(1.0)[a]	-	-	(1.0)[a]	-	(1.0)[a]	-
Soil Cores							
Near foundation	1.0	1.0	-	1.0	-	(1.0)[a]	-
Property boundary	-	-	-	(1.0)[a]	-	-	-
Drinking Water	1.0	-	-	1.0	-	(1.0)[a]	-
Wipe-Dust	-	3.0[g]	-	-	-	-	-
Wipe vs. Vacuum[d]	-	-	-	-	-	-	-
Field QC							
Vacuum-dust blank	1.0	1.0	1.0	1.0	1.0	1.0	1.0
Vacuum-dust duplicate	0.1	0.1	0.1	0.1	0.1	0.1	0.1
Soil blank/duplicate	1.1[e]	1.1[e]	-	1.1[e]	-	1.1[e]	-
Water blank/duplicate	1.1[e]	-	-	1.1[e]	-	1.1[e]	-
Wipe dust blank & duplicate[d]	-	-	-	-	-	-	-
Total Collected for Analysis	12.3	13.7	9.1	12.3	9.1	10.3	9.1
Total Collected and Stored	3.0[f]	0.5[f]	1.0[e]	3.0[f]	1.0	4.0[f]	1.0
Total Samples[h]	15.3	14.2	10.1	15.3	10.1	14.3	10.1

a Collected, prepared and stored for later analysis.
b Sample Air Duct if possible, if not then collect upholstery sample.
c Collect only upholstery samples in homes that did not have such a sample at Pre-R&M.
d Seventy-five pairs of side-by-side wipe/vacuum dust samples from floors, window sills & window wells will be collected as a substudy in a separate group of dwellings; field blanks and duplicates will be included.
e This includes 1.0 field blanks (50% will be analyzed, 50% will be stored) and 0.1 field duplicates.
f See footnote "e" for soil and water QC.
g Estimated average number of wipe samples required by the Maryland Department of the Environment for regulatory purposes. (Expected range 2-10 samples per unit.)
h Pre- & Post-R&M campaigns will include all 75 R&M dwellings. Follow-up campaigns will include 60 R&M dwellings (20 dwellings of each R&M level).
i All 75 R&M dwellings will be sampled at Pre- and Post-R&M. Sixty R&M dwellings will be sampled at each follow-up campaign (20 dwellings each of R&M Levels I-III.

Table 2.4B Summary of Environmental Sampling Planned per Modern and Previously Abated Control Dwelling by Campaign

Sample Type	Enroll	2nd Campaign	3rd Campaign	4th Campaign	5th Campaign
Vacuum-dust					
Perimeter floor composite	3.0	3.0	3.0	3.0	3.0
Window sill composite	2.0	2.0	2.0	2.0	2.0
Window well composite	2.0	2.0	2.0	-	2.0
Air duct/upholstery	(1.0)[a,b]	(1.0)[a,c]	(1.0)[a,b]		(1.0)[a,b]
Int. Entrance	1.0	1.0	1.0	1.0	1.0
Ext. Entrance	(1.0)[a]	(1.0)[a]	-	(1.0)[a]	-
Soil Cores					
Near foundation	1.0	1.0	-	(1.0)[a]	-
Property boundary	-	(1.0)[a]	-	-	-
Drinking Water	1.0	1.0	-	(1.0)[a]	-
Field QC					
Vacuum-dust blank	1.0	1.0	1.0	1.0	1.0
Vacuum-dust duplicate	0.1	0.1	0.1	0.1	0.1
Soil blank/duplicate	1.1[d]	1.1[d]	-	1.1[d]	-
Water blank/duplicate	1.1[d]	1.1[d]	-	1.1[d]	-
Total Collected for Analysis	12.3	12.3	9.1	10.3	9.1
Total Collected and Stored	3.0[e]	4.0[e]	1.0	4.0[e]	1.0
Total Samples	15.3	16.3	10.1	14.3	10.1

[a] Collected, prepared and stored for later analysis.
[b] Sample air duct if possible, otherwise collect upholstery sample.
[c] Collect only upholstery sample in homes that did not have such a sample at Enrollment.
[d] This number includes 1.0 field blanks (50% will be analyzed, 50% will be stored) and 0.1 field duplicates.
[e] See footnote "d" for soil and water QC.

If these incentives are not sufficient, we would use feedback from participating families and community organizations in planning for additional or alternative forms of incentives. Additional incentives may include group activities for the children such as skating parties at a local skating rink to help promote a feeling of good will in the community toward the Project.

2.3.2 Measurement Processes

Soil, dust, water and blood will be analyzed at the Kennedy Krieger Institute's Trace Metal Laboratory using established analytical methods. Microwave digestion will be used for soil, vacuum-dust and water samples. The KKI method for bioavailable lead will be used for dust wipes. Initial analysis of dust and soil digestate will be carried out using Inductively Coupled Plasma (ICP) with a crossover to Graphite Furnace Atomic Absorption Spectrometry (GFAA) at low levels (see section 4.0). Analytical measurements will be carried out on drinking water digestates using GFAA. The procedure for soil includes a pre-digestion step of sample drying and homogenization to improve precision. The procedure for vacuum dust includes a pre-digestion step of sample drying and weighing. Analysis by GFAA using nitric acid (no HCl) digestion will be used for all samples regardless of the analytical technique being used. Wipe-dust samples will be extracted and analyzed by FAA using procedures employed in past Kennedy Krieger Institute studies.

Blood samples will be analyzed using anodic stripping voltammetry (ASV) for clinical monitoring purposes and by graphite furnace atomic absorption spectrometry (GFAA) for research purposes. It is expected that GFAA methods will be more precise and accurate than ASV methods. In this study, samples will be run by both ASV and GFAA methods until it is determined by EPA based on statistical analysis of QC data that analysis by GFAA alone is sufficient; these two methods will be compared using the same external proficiency standards. Protocols for sample preparation and analysis are found in the appendices. A protocol for blood lead analysis by GFAA is provided in Appendix AA.

2.3.2.1 Instrument and Method Performance Characteristics

Analytical measurements of lead in environmental samples will be carried out as follows: a) Vacuum-dust and soil - ICP/GFAA b) water digestates - GFAA according to SW-846 with modifications c) dust wipes - FAA d) blood - ASV and GFAA. The specifications for the analytical method and instrument performance characteristics for all methods are attached in the appendices. Our backup instrument for vacuum-dust and soil is FAA. Estimated limits of Quantitation (LOQ) and likely ranges of lead values are shown in Table 2.12 by sample type.

2.3.2.2 Design of Measurement Processes

The three measurement processes to be applied to the analysis of dusts, soils, and drinking water in this study are ICP/GFAA (Vacuum-dust and soil), GFAA (drinking water), and FAA (wipe-dust).

Sample Preparation

Sample preparation criteria are highlighted in Table 2.13. The entire content of the microwave digestion liner containing the vacuum dust sample will be digested after drying at 110 °C overnight. Gravimetrics analysis is then performed in the KKI laboratory to determine the dry weight of dust collected. A specific procedure for gravimetrics analysis on the microwave digestion liners in the laboratory is included in Appendix I. Reporting units will be in micrograms Pb per gram of dust and micrograms per square foot of surface sampled. The methods for preparation and analysis of wipe samples will be the same as those used in past studies by the Kennedy Krieger Institute and are described in Appendix U. Values will be reported in terms of $\mu g/ft^2$.

The sample sizes to be digested for soil cores will be 0.5 g ± 0.020 g of soil. Soils will be dried at 110 °C overnight and then homogenized and sub-sampled for analysis. A specific procedure for

the handling of soil samples including drying and mixing steps is included in laboratory protocols. Reporting units will be in micrograms Pb per gram of soil (dry weight). A loss on drying will not be measured or reported. Water content of the soils is not a data objective in this study.

The sample size to be digested for water will be 45 mL ± 0.5 mL of drinking water. See section 4.0 regarding procedures for handling drinking water samples in the laboratory. Reporting units will be in μg Pb/L of drinking water.

The sample size of blood to be collected is expected to be 1.5 mL of blood. See Appendix K for a procedure for collecting and handling blood specimens in the laboratory.

The types and numbers of QC samples originating in sample preparation are shown in Table 2.14. Duplicate spikes, as opposed to duplicate samples, are used for precision estimates. Duplicate samples are homogenized samples which have been subsampled. These types of samples could be used for interlaboratory comparisons. Duplicate spikes are the same except that they are spiked with a known quantity of analyte. If the original sample does not have any detectable analyte present, then the laboratory will report a "less than" value. Precision calculations cannot be performed with a "less than" value. However, if the sample is spiked with analyte, then a positive value will be reported. Consequently, use of duplicate spikes assures that precision estimates can be calculated. Duplicate spikes will be used in this study to assure that precision data will be available. However, when the spiked amount is less than ten percent of the sample value, the spike recovery will not be considered relevant for control charting. Data quality objectives for sample preparation QC samples are listed in section 2.1.3.

TABLE 2.13

Sample Preparation Criteria for Environmental Samples

Criteria	Specification
Preparation & handling of vacuum-dust	Post field gravimetrics to determine sample dry weight
Vacuum-dust sample	Digest total dust sample
Vacuum-dust final dilution volume	50 mL
Wipe-dust sample	Wipe and dust used for extraction
Wipe-dust final dilution volume	30 mL
Preparation of soil samples	Drying, homogenizing and sieving
Soil sample size	0.5 g ± 0.02 g
Soil final dilution volume	50 mL ± 0.5 mL
Water sample size	45 mL ± 0.5 mL
Water final dilution volume	50 mL ± 0.5 mL

TABLE 2.14

Sample Preparation Quality Control Samples for Environmental Samples

SAMPLE TYPE	FREQUENCY (per Digestion Batch)
Spike sample[1]	1 per digestion batch of 24 samples
Spike duplicate[1]	1 per digestion batch of 24 samples
Method blank	1 per digestion batch of 24 samples
Reference material[2]	1 per digestion batch of 24 samples (for dust and soil, #2704; for water SRM#1643c)

1. Spikes and spike duplicates will be performed on real world samples for soil and water and on reagents for dust samples since dust samples cannot be uniformly divided. Spike levels will be made to achieve a final post digestion concentration of 10 µg Pb/mL for soils, 10 µg/mL for dusts (for GFAA 10 ppb is upper limit), wipe-dust 3.23 µg/mL, and 0.5 µg/mL for water samples.

2. Reference material samples will be inserted as performance sample into the sample stream by the technician doing the sample preparation in a manner which would be blind to the sample analyst. The laboratory will expect to digest a minimum of 24 field samples per day. The reference material is considered a field sample to the laboratory and will serve as an audit sample for the laboratory.

2.4 Effects of Reduction in Study Size

This section provides the information on the effects of reduction in (a) number of control dwellings from 50 to 30 (modern and previously abated dwellings) (b) number of R&M group environmental data collection campaigns (from 8 to 7) (c) the number of individual vacuum dust samples per dwelling (d) the number of other sample types.

2.4.1 General Results

The traditional sample size formula for detecting a difference of size δ between two population means using a two sample Student's t test with significance level α, power $1 - \beta$ and equal variance σ^2 in the two populations is given by

$$n \geq \frac{2\sigma^2(z_{1-\alpha} + z_{1-\beta})^2}{\delta^2}$$

or in terms of the standardized difference $\Delta = \delta/\sigma$

$$n \geq \frac{2(z_{1-\alpha} + z_{1-\beta})^2}{\Delta^2}$$

The actual test statistic uses values from the Student's t distribution but using z values results in little difference when calculating sample sizes.

From the above formula for a sample size of kn we can detect a difference Δ_k of magnitude satisfying

$$\Delta_k \geq \frac{\sqrt{2}(z_{1-\alpha} + z_{1-\beta})}{\sqrt{kn}}$$

If $k = 1$ we have the size of the full study while for $0 < k < 1$ we obtain the effect of reducing the study size by $100(1 - k)\%$. Thus if Δ_F is the difference detectable in the full study we have

$$\Delta_k = \frac{\Delta_F}{\sqrt{k}}$$

Thus we have the following table:

Effect of 100(1 - k)% Reduction in Study Size

k = 1	$\Delta_k = \Delta_F$
k = .9	$\Delta_k = 1.05\Delta_F$
k = .8	$\Delta_k = 1.11\Delta_F$
k = .7	$\Delta_k = 1.20\Delta_F$
k = .6	$\Delta_k = 1.29\Delta_F$
k = .5	$\Delta_k = 1.41\Delta_F$
k = .4	$\Delta_k = 1.58\Delta_F$
k = .3	$\Delta_k = 1.83\Delta_F$
k = .25	$\Delta_k = 2.00\Delta_F$

2.4.2 Application to the R & M Study

The R & M study hinges on the analysis of change in children's blood leads and on the comparison of different methods of intervention using longitudinal data analysis. Thus the sample size and effect detection criteria discussed in the preceding sections are not strictly applicable. They do, however, provide general guidelines as to the effects of a reduction in the magnitude of the study.

The reduction of the number of control houses from 50 to 30 represents a reduction of 40% or a k of .6. The reduction in the number of houses in the follow-up campaigns from 25 to 20 will mean that comparisons of R & M groups will allow us to detect a standardized difference of 1.11 times the standardized difference in the full study. Comparisons with controls will allow detection of a standardized difference which is 30% larger than in the full study.

For the longitudinal analysis of changes in blood lead and dust lead levels the reduction in sample size corresponding to the elimination of one sampling campaign leaves us with seven campaigns instead of eight. From the tables in Rochon we see that seven campaigns require a sample size of 20 with correlations of .3 for a standardized difference of .9, a sample size of 20 with correlations of .6 for a standardized difference of 1.1 and so on. Since our pilot work indicates that the expected correlation is at

least .5 the reduction in the number of campaigns is expected to have little impact on the differences that we will be able to detect.

2.4.3 Effect of Compositing

One of the major reductions in the R & M study is achieved by increased compositing of samples across rooms. As the R & M pilot study showed the major source of variability within a house is the within room component, accounting for at least 75% of the variability. Thus, by compositing across rooms we achieve significant reduction in the total number of samples with marginal increase in σ^2, the basic population variance used in the formulas for sample size calculation and effect detection level. The inflation factor for the detection level is $\sqrt{1.33} = 1.15$.

2.4.4 Effect of Reduction in Q-C Samples

The reduction in quality control samples has no direct impact on the ability of the study to detect differences. The reduction does effect the validity of the results if quality of sampling and laboratory analyses are in question. The results of our pilot study indicate a high level of quality and we expect no detrimental effects from this reduction.

2.4.5 Effect of Reduction in Other Areas

The proposed reduction in study size definitely effects the study's ability to investigate further room-to-room variability and estimate other relationships of interest (correlation of individual room floor dust levels and window sill dust levels, etc.). However, we will still be able to study the relationship between composites of floors, window sills and window wells.

Although we have reduced the frequency of collection of exterior entry way dust samples and exterior property boundary soil samples we will still have the ability to investigate the potential of lead tracking from outside to inside. Similarly eliminating one interior entrance way and one exterior entrance way dust sample does not prevent us from examining this pathway as well.

2.4.6 Conclusions

The proposed reduction in study size for the R & M study has a modest, but not disastrous, impact on the differences which can be detected.

3.0 SAMPLE COLLECTION
3.1 Sampling Procedures

The following sections describe sampling procedures for children's blood, interior house dust, soil, and drinking water. The collection procedure for blood is that of the Kennedy Krieger Institute's Lead Poisoning Clinic. Dust sample collection will be done using a modified and portable HVS_3 cyclone sampler. Vacuum samples of surface dust will be collected from floors (carpeted or uncarpeted), window sills and window wells using a 100 mL microwave digestion liner as a collection device. See revised Appendix L for the HVS_3 sample collection protocol.

Air Duct:

An air duct is defined as one of a series of hollow passageways/channels through which heated, cooled or room air is conveyed into the interior living environment. For purposes of the study, Field Team Leaders will be responsible to determine which if any air duct can be sampled based on accessibility and availability of the proper surface (i.e. it has a non-vertical surface that can be reached with the extended flexible sampling nozzle).

Upholstery:

For purposes of the study, a one square foot dust-vacuum sample will be taken from the largest piece of fiber upholstered furniture in the main living area of study dwellings. In lieu of such a piece of furniture in the main living area, the Field Staff will sample the most frequently used fiber-upholstered item elsewhere in the house.

Interior and Exterior Entry Way Samples:

Interior entry way dust vacuum samples will be collected from the entry way closest to the side of the dwelling that has exterior soil. If there is no exterior soil, then the main interior entry way will be sampled. If both the front and back of the dwelling have soil, then the interior entry way on side of the house with both foundation and property boundary soil available for sampling will be selected; otherwise, preference will be given to the interior entry way on side of the house with foundation soil available for sampling. If both the front and back of the dwelling have only property boundary soil available for sampling, then the side of the house with the main entry way will be selected for sampling. The exterior entry way dust sample will be collected from the same entry way as the interior entry way sample. If the

exterior entry way has soil then a soil core sample will be collected in lieu of a vacuum dust sample.

Soil:

The soil sampling sites for soil core composites will be three randomly selected sites along the foundation and/or property boundary.

3.1.2 Equipment

Vacuum samples of surface dusts are collected using an unloaded 100 mL microwave digestion liner inserted in a cyclone sampler. The sampler is attached to a Dirt Devil vacuum. Sampling equipment is readied for use by removing the cap from the microwave digestion liner.

3.4 Sample Handling for Environmental and Blood Samples

Detailed procedures for handling environmental samples in the field are presented in Appendices J, L, M and N. Soon after the blood is collected in the Lead Clinic (lobby level of the Institute) it will be taken upstairs by Lead Clinic personnel to the blood-lead analysis area of the Trace Metals Laboratory located on the 1st floor of the Institute. The sample will be given to the Laboratory Technician for sample analysis or it will be placed in the laboratory's refrigerator and stored for analysis at a later time. After analysis by ASV, the blood specimens will be sent to the main Trace Metals Laboratory for analysis by GFAA and storage.

4.0 LABORATORY ANALYSIS AND MEASUREMENTS

This section covers the general analytical and quality control procedures to be used. The detailed methods for preparation and analysis of the dust (vacuum and wipe), soil, drinking water and blood sample matrices are included in Appendices R - W and AA.

4.1 Analysis Procedures

Table 4.1 summarizes the pre-preparation, preparation, and analysis procedures to be used for each sample matrix. The analytical procedures to be used are as follows: Vacuum-dust samples--Microwave digestion with ICP/GFAA analysis (Appendices R, T, and V); Soil samples--Microwave digestion with ICP/GFAA analysis, (Appendices R, T, and V); Water samples--Microwave digestion with GFAA analysis (Appendices R and T); Wipe-dust - HCl extraction with FAA analysis (Appendices T and U); and, Blood Samples--Anodic Stripping Voltammetry (ASV), (Appendix S) and Analysis of Whole Blood Samples by GFAA (Appendix AA).

For the dust (vacuum) sample matrix, gravimetric analysis will be performed after field collection and prior to digestion. Gravimetric analysis procedures for dust are listed in Appendix I.

Soil Samples will be dried, sieved, and homogenized prior to digestion. This procedure is detailed in Appendix R.

Following the pre-preparation techniques, dust (vacuum) and soil samples will be digested using microwave digestion. Waters will not require pre-preparation and will be digested in the microwave directly. Wipes will be extracted using the traditional KKI method. The GFAA option using nitric acid as the primary digestion medium will be used on all samples, regardless of the analytical technique to be applied. Drinking water samples will be digested using EPA SW-846 Method 3020 for aqueous samples. Dilution with an electrolyte will be required for ASV analysis. (See section 4.1.4 for composition of electrolyte solution).

4.1.1 Reference Materials

Calibration and spiking materials used for dust (vacuum and wipe), soil, and drinking water are obtained as certified standards from Perkin-Elmer or other commercial suppliers. Calibration materials for blood are based on reference standards and standards prepared by the Trace Metals Lead Laboratory.

The National Institute of Standards and Technology (NIST) Standard Reference Materials (SRM) will be used for method accuracy determinations. For evaluation of microwave digestion techniques for vacuum-dust and soil and HCl extraction for wipe-dust, SRM#2704

(Buffalo River Sediment) will be used. One SRM will be used to monitor each batch of samples. SRM1643c (Trace Metals in Water) will be used to monitor the digestion procedure for water. See Appendix W for a protocol for preparation and handling of reference materials. Calibration verification and other QC procedures for blood are described in Appendix S and Appendix AA.

National Bureau of Standards standard reference material SRM#955 (lead in porcine blood) is currently available for use as a primary standard for analysis of lead in blood by GFAA. For ASV, we use human blood containing biologically bound lead which has been analyzed by the ultimate reference method for lead; namely, stable isotope dilution-mass spectroscopy (ID-MS) by Dr. William Manton, University of Texas. Dr. Manton will only do this if research is involved. These primary standards are kept at -70 degree (C) in small aliquots for use as needed. The present set of primary standards contains blood-lead levels ranging from 3-42 μg Pb/dL.

Secondary standards are prepared by spiking bovine blood obtained from a nearby abattoir. Secondary standards (spiked bovine blood prepared in this laboratory) are run using the ID-MS values as reference standards. Secondary bovine standards are kept in separate aliquots (5 ml) at -20^{0}C. The present set of secondary standards contains the following values: 2, 15, 24, 32, 46, 66, 86 μg Pb/dL. The highest values are extrapolated because we have been unable to obtain human blood with high lead levels. These secondary standards are used in day-to-day work for initial calibration of the ESA 3010-A ASV instrument and to maintain calibration throughout the day. One or more secondary standards is run after every four sample readings, choosing standards which bracket the last patient specimen run.

4.1.2 Instrumentation

Primary instrumentation at the Kennedy Krieger Institute Trace Metal Laboratory for the analytical efforts are an Inductively Coupled Plasma Spectrometer (ICP), Graphite Furnace Atomic Absorption Spectrophotometer (GFAA), and a backup Flame Atomic Absorption Spectrophotometer (FAA) instrument. The ICP Plasma 1000 will be supplied and serviced by Perkin-Elmer as will the 5100 Graphite Furnace. Recent acquisitions include a CEM Model 2100 microwave digestion system, a Micromedic Digiflex pipettor (for blood dilution and addition of reagents prior to analysis by GFAA), and a DataFlow Sato 8400 barcode label printer.

For dust and soil analysis, the ICP will be the primary source of measurement with the GFAA used for low concentrations. For water samples the GFAA will be the primary instrument. A portable spectrum X-Ray fluorometer is used by City Homes in testing paint.

TABLE 4.1

Pre-Preparation, Preparation, and Analysis Procedure Summary

Sample Type	Pre-Preparation Summary	Preparation Summary	Analysis Summary
Dust-Wipe	none	Digest whole wipe using 0.15 M HCl	FAA
Dust-Vacuum	Post-field gravimetrics	Digest using 1:1 HNO_3: H_2O with microwave heating	ICP/GFAA
Soil	Sample drying and homogenization	Digest using 1:1 HNO_3: H_2O with microwave heating	ICP/GFAA
Drinking Water	none	Digest using 1:1 HNO_3: H_2O with microwave heating	GFAA
Blood	Stabilized in EDTA during sampling	N/A	ASV and GFAA

For blood-lead analysis, we will use an Environmental Sciences Associates, Inc. Rapid Blood Lead Analyzer (ESA Model 3010-A, Bedford, MA) anodic stripping voltammeter (ASV) and a Perkin Elmer 5100 GFAA instrument.

4.1.2.2 Demonstration of Achievements of Instrument Performance Requirements

Parameters that will be monitored to demonstrate instrument performance will be instrument sensitivity and reproducibility based on observed response versus expected or historical response. The instrument performance will be demonstrated on a daily basis to document the necessary sensitivity to achieve the objective LOQs as shown in section 2.1.3. Reproducibilities can be demonstrated on a daily basis of instrument response for the analyte. In addition, instrument stability will be monitored using instrument check standards. Initially, each analytical run will include at least 5 replicates of the low standard for the purpose of calculating the instrumental detection limit (IDL). At some point in the future, and based on the stability of historical response, the Laboratory QC Officer may determine that less frequent IDL determinations are needed (e.g. weekly or monthly).

4.1.3 Instrument Calibration

The instrument calibration procedures are provided in the attached methods in Appendices S through V. Appendix AA describes the analysis of whole blood samples using GFAA. For blood-lead analysis, secondary standards are used after every four analyses to detect and correct for drift.

4.1.5 Glassware and Miscellaneous Supplies

All glassware and miscellaneous supplies must conform with the requirements specified in the analytical methods. Glassware must be shown to be free from contamination either by batch checking or by the inclusion of method blanks. All new glassware will be washed according to protocol before being released for laboratory analysis.

We use disposable borosilicate 100 μL pipettes to measure and dispense the blood samples. The polypropylene analysis tubes are decontaminated after each use.

4.1.6 Contamination and Loss Avoidance

Laboratory contamination will be avoided by thoroughly cleaning laboratory glassware/plasticware before use (Appendix X). In addition, the contents of the acid cleaning tanks used for glassware/plasticware preparation are changed every week. Additionally, three items of glassware/plasticware will be selected from each batched washed and screened for lead levels. See Appendix X. If any of the three screened items has an absorbance greater than the expected absorbance of method blanks, then the entire batch will be rewashed and rechecked.

Sample containers will be cleaned by the laboratory staff. In addition, the dust sampling materials will be prescreened for possible lead contamination prior to submission to the field. Sample bottles, centrifuge tubes, soil core liners, and microwave digestion liners have already been adequately tested for background lead and were found to have negligible amounts. As part of this process, representative samples from each new lot of sample substrates will be digested and analyzed by GFAA. This screening will be performed using randomized sampling of each lot.

4.4.2 Security

Field sampling will likely take place in housing located in inner-city neighborhoods that may have high crime rates. In these situations, security of the field teams becomes an issue. Field teams will work in teams of 2-3 persons and will perform field work during daylight hours to the extent possible. Study vans will be clearly marked with the Kennedy Krieger Institute logo.

TABLE 4.2 Number and Type of Control Charts

Item Charted	Sample Type	Number of Control Charts	Value Charted	Use of Data
Reference Material SRM #2704	Dust-vac	1	% recovery	To assess accuracy of laboratory processing of samples within a single batch AND between sub-batches
Reference* Material SRM#2704	Dust-wipe	1	% recovery*	To assess accuracy of laboratory processing of samples within a single batch
Reference Material SRM #2704	Soil	1	% recovery	To assess accuracy of laboratory processing of samples within a single batch
Reference Material SRM # 1643C	Water	1	% recovery	To assess accuracy of laboratory processing of samples within a single batch
Reference Material SRM#955	Blood	1	% recovery	To assess accuracy of laboratory processing of samples within an analytical run

* Extraction using HCl is not expected to attain full recovery compared to nitric acid digestion. Consequently, the percent recovery is not critical to QC charting.

TABLE 4.2

Number and Type of Control Charts
(Continued)

Item Charted	Sample Type	Number of Control Charts	Value Charted	Use of Data
Spikes	Dust-vac	1	% recovery	To assess accuracy of laboratory processing of samples within a single batch
Spikes	Dust-wipe	1	% recovery	To assess accuracy of laboratory processing of samples within a single batch and to test for matrix interferences
Spikes	Soil	1	% recovery	To assess accuracy of laboratory processing of samples within a single batch and to test for matrix interferences
Spikes	Water	1	% recovery	To assess accuracy of laboratory processing of samples within a single batch and to test for matrix interferences

TABLE 4.2

Number and Type of Control Charts
(Continued)

Item Charted	Sample Type	Number of Control Charts	Value Charted	Use of Data
Spike Duplicates	Dust-vac	1	% range	To assess accuracy of laboratory processing of samples within a single batch/ability of lab to replicate results
Spike Duplicates	Dust-wipe	1	% range	To assess accuracy of laboratory processing of samples within a single batch/ability of lab to replicate results
Spike Duplicates	Soil	1	% range	To assess accuracy of laboratory processing of samples within a single batch/as above
Spike Duplicates	Water	1	% range	To assess accuracy of laboratory processing of samples within a single batch/as above

TABLE 4.2

Number and Type of Control Charts
(Continued)

Item Charted	Sample Type	Number of Control Charts	Value Charted	Use of Data
ICV	Soil	1	response	To verify consistency of day-day operation of the ICP/GFAA
ICV	Dust-vac Water	1	response	To verify consistency of day-day operation of the ICP/GFAA
ICV	Dust-wipe	1	response	To verify consistency of day-day operation of the FAA
ICV	Water	1	response	To verify consistency of day-day operation of the GFAA

TABLE 4.2

Number and Type of Control Charts
(Continued)

Item Charted	Sample Type	Number of Control Charts	Value Charted	Use of Data
CCV	Dust-vac	1	response	To verify consistency of day-day operation of the ICP/GFAA
CCV	Dust-wipe	1	response	To verify consistency of day-day operation of the ICP/GFAA
CCV	Soil	1	response	To verify consistency of day-day operation of the FAA
CCV	Water	1	response	To verify consistency of day-day operation of the GFAA

TABLE 4.3

Control Chart Values

Item Charted	Sample Type	Target Value	Initial Warning Limit	Initial Control Limit
Reference Material	All but wipe-dust[1-3]	100 % recovery	± 20%	± 30%
Spikes	ALL	0% range	± 20%	± 30%
Spikes	ALL	100% recovery	± 20%	± 30%
ICV[4]	ALL	100% recovery	± 20%	± 30%

1 Extraction using HCl is not expected to attain full recovery compared to nitric acid digestion. Consequently, the percent recovery is not critical to QC charting.

2 Recovery of reference materials for dusts may have a bias due to the inclusion of uncertainty related to the method of preparing the reference materials (i.e. vacuumed into blank microwave digestion liners and weighed onto blank wipes). Consequently, for dust, SRM material will not be prepared using the cyclone sampler and will be weighed directly into the digestion liner for analysis.

3 Unlike SRM#2704 (Buffalo River Sediment), recovery of SRM#1646 (Estuarine Sediment) following nitric acid digestion maybe below expected values due to high silica content (31%) and lead bound as silicates. Consequently, one SRM- SRM#2704 will be used.

4 ICV = Initial Calibration Verification standard used for ICP, GFAA and FAA instruments.

7.0 QUALITY ASSURANCE DELIVERABLES

Quality Assurance deliverables will include QAPjP modifications, monthly progress reports, laboratory system and performance audit (including control charts) reports, data audits and packages, interim reports and a final report. There will be two types of interim reports: (1) interpretation of data collected to date based on formal statistical analyses and (2) descriptive summaries of data collected during a single campaign. Reports of descriptive summaries will be brief and will not involve the fitting of the statistical models to data.

- Interim Data Analysis Reports:

FY1993 (Assuming a start date in December, 1992)

a. Report on Enrollment Activities
b. Summary of lead (Pb) levels in dust, soil, drinking water, and blood at time of enrollment by study group.
c. Report on comparison of side-by-side wipe and vacuum dust samples.
d. Draft preliminary analysis of pre- versus immediately post-R&M Levels I-III.

FY1994 (Assuming a start date in December, 1992)

e. Enrollment dust lead (PbD) levels in previously abated dwellings compared to pre-abatement and clearance PbD levels.
f. Enrollment PbD levels in modern dwellings compared to enrollment levels in previously abated dwellings.
g. Summary of PbD levels in R&M homes at two months post-R&M.
h. Preliminary analysis of six month data on R&M Levels I-III.

FY1995 (Assuming a start date in December, 1992)

i. Summary of Pb levels in dust, soil and drinking water by study group at 12 months post-R&M.
j. Preliminary analysis of 18-month data on R&M Levels I-III.

FY1995 (Assuming a start date in December, 1992)

k. Analysis of 24-month data for final report, which will contain instrument performance characteristics and the results of other quality control analyses.

Reports b, g and i are summaries of descriptive statistics for the data collected at a single campaign.